INSTRUCTIONS FOR USE
LUMENUS LC INJECTION SYSTEM

INDICATION FOR USE
Lumenus LC Injection System is intended for use in implantation of the Saline II, Saline I, Saline III, and any approved BIO, in which the labeling specifies use of this syringe to insert the wire into the capsule bag following extracapsular extraction.

DESCRIPTION
The system consists of the following components:
- Titanium Injector (1-0179) (See Fig. 6)
- The syringe type syringe is intended to be used with the following cartridges: L176, L2015, L2622, Carf4, Carf5, and Carf6. It is used to inject the intracapsular lens through an incision into the capsule bag. The syringe is manufactured from titanium and is reusable (following decontamination, inspection, and sterilization). The syringe is supplied sterile and must be cleaned, inspected, and sterilized prior to initial use.
- Titanium Injector (1-0172) (See Fig. 7)
- The syringe type syringe is intended to be used with the following cartridges: Carf6, Carf7, Carf8, and Carf9. It is used to inject the intracapsular lens through an incision into the capsule bag. The syringe is manufactured from titanium and is reusable (following decontamination, inspection, and sterilization). The syringe is supplied sterile and must be cleaned, inspected, and sterilized prior to initial use.
- LC-300 Cartridges (See Fig. 9)
- The sterile single use cartridges are used to hold the intracapsular lens prior to implantation. The L176, L2015, Carf4, Carf5, and Carf6 cartridges have a lip diameter of 1.5 mm and are packaged sterile. The L2015 cartridge is a lip diameter of 2.4 mm and is packaged sterile. The Carf1 cartridge has a lip diameter of 1.7 mm and is packaged sterile. These should be safely discarded after use as medical waste.
- Silicone Cushion (See Fig. 8)
- A cushion, which is supplied with each cartridge, is used to provide a cushion when inserting intracapsular lenses. The tip is sterile and is designed for single use and should be safely discarded after usage as medical waste.
- Lens Leader (See Fig. 9)
- The lens leader is used to ensure proper placement of the intracapsular lens into the capsule pocket. The leader is supplied sterile and must be cleaned, inspected, and sterilized prior to initial use.

HOW TO USE THE LUMENUS CARTRIDGE

PREPARATION
1. Prior to usage, ensure that the titanium injector and lens leader have been properly cleaned/decontaminated/inspected and sterilized. Once sterile, they may be transferred into the operative sterile field.
2. In the sterile field, place both the 5ml syringe and place the cartridge and silicone cushion (accompanied by the silicone cushion leader) onto the sterile operating room tray.

LOADING THE LEADER INTO THE CARTRIDGE INJECTOR ASSEMBLY

To ensure that the intracapsular lens is seated and works effectively and correctly, it is essential to follow the correct procedure when loading the lens into the cartridge. The following is a step-by-step guide that explains how to load the injector:

Note: A few items were used in the instructions for use for suitability purposes only.

1. For Carf6 cartridges:
   - Open the cartridge flaps and throw each end of the chamber with saline. (See Fig. 1).
   - Place lens leader into the carrot flaps and throw each end of the chamber with saline. (See Fig. 1).
   - Making sure that the plunger is exposed, use the applicator to fill the silicone cushion into the plunger. (See Fig. 2).
   - Remove the lens from the barrel. Holding the top of the cartridge open, slightly wider than 90°, place the lens in the cartridge as you would want it in the eye. Place a partially open pass of saline, gelled saline (i.e. McPherson, Becton Dickinson) over the entire lens (including the haplot). (See Fig. 1).
   - Allow the flaps to close to 10° to 10° away. (See Fig. 1).
2. Note: It is imperative that the QL be injected into the eye within two minutes of removal from the saline filled vial. Due to the hyaluronic nature of the lens, extended periods of time outside of the vial will cause the lens to dehydrate and subsequently become damaged during the injection process.
3. Using an appropriate instrument, ensure that the haplot are in the correct position and seated in the cavity. Ensure that the haplot are not at rest. Once the haplot are seated and in the cavity chamber from the side and make that no part of the haplot are caught in the flap, if it is imperative to ensure that the trailing haplot is tucked within the boundaries of the chamber prior to injection. Place the lens leader’s tab end into the back of the chamber, while the flaps are still closed and advanced the lens from the chamber in the same manner. (See Fig. 4).
4. Ensure that the lens leader is advanced to its fullest extent, so that the lens is to the cavity tip (proximal). The cartridge tip is now ready to be used in the chamber.
5. Before the use of the lens, be sure to check that the lens is properly placed in the cartridge. The lens can lead to damage during injection/implantation.
6. Ensure that the plunger is retracted so far as possible, place the lens barrel first into the housing and push it in as far as it will go. (See Fig. 1).
7. Deploy the injector plunger so that the silicone cushion fills into the back of the cartridge chamber and advance it forward until you can just see the tip in the barrel. (See Fig. 1).
WARNING
1. Clean, inspect and sterilize the injector and lens loader before initial use and prior to subsequent use.
2. The cartridges are intended for Single use. Do not re-sterilize or reuse.
3. The cartridges are sterile unless the external pouch is damaged. If the packaging is damaged, do not use.
4. Discard used cartridges in medical waste containers.
5. Do not use aggressive detergents or any kind of detergents. Never use buffered saline solution for rinsing the instruments.
6. The LC injection system is intended for use only with the intracocular lens with which it has been validated.
7. Proper surgical procedure is the responsibility of the individual surgeon. The surgeon must determine the suitability of any particular procedure based upon his/her training and expertise.

CARE INSTRUCTIONS
- None known.
- CLEANING INSTRUCTIONS
  MANUAL
  - Prior to initial use and immediately after every use thereafter, soak the injector and lens loader devices in warm dilute water (36-45°C) for a minimum of five (5) minutes.
  - At the end of the flow (2) minutes, and when submerged in the warm water (200 mL), manipulate the plunger, depending on the injection mechanism, on push or twice, by simulated plunging, the full length of the device at least ten (10) times to loosen up the soil in the syringe.
  - Next, wash the syringe with water, rinse the device and its accessories with a soft-bristled brush. Repeal this step with the plunger inserted fully down the device as well as with the plunger in the fully retracted position.
  - Visually inspect the device and confirm the absence of gross debris. If gross debris remains, re-immerses the device in the warm water and continues scrubbing the device with the soft-bristled brush until confirmation that it is visually free of gross soil debris.
- RINSING
  - Rinse the injector and lens loader devices from the remaining water and then from under running cold water for 30 to 60 seconds. While rinsing, manipulate the plunger rapidly back and forth to wash the elimination of debris from the interior of the syringe.
- Use the device out to dry with the plunger fully inserted.
- NOTE: Do not use rinse if wear or damage is apparent. This use includes, but is not limited to, desiccation, chipping or material degradation. Be sure to clean any contamination appearing on the device prior to sterilization as this could cause wear or damage to the device(s).
- NOTE: Should any other type of cleaning method be used, the user must verify its effectiveness prior to sterilization and subsequent use.
- STERILIZATION AND RESTERILIZATION OF THE INJECTOR
  After the device(s) have been properly cleaned, it is recommended that it be sterilized in accordance with one of the following standards:
  - Use national standards.
- STERILIZATION CYCLE PARAMETERS
- UNWRAPPED ITEMS
  1. Gravity displacement vessel. The recommended minimum exposure time and temperature for the injector and lens loader is three (3) minutes at 121°C (250°F), with a load size of three (3) reusable surgical instruments in three adequate common to healthcare facilities. The recommended dry time is a maximum of 1 minute.
  2. NOTE: This validated cycle represents a worst-case scenario representing the shortest duration sterilization cycle which effectively sterilizes the instruments. This is a scenario which is most likely to be used by health care facilities due to the type of equipment most readily available to sterilize surgical instruments. Should any other type of sterilization method or parameters (i.e., vacuum/temperature/contaminants, without there is a unique configuration, 10 min, 121°C) be used, the user must verify its effectiveness prior to use.
  3. NOTE: Do not re-enter the lens cartridges. The cartridge is a Single Use Only component.
- WRAPPED ITEMS (AN FDA CLEARED WRAP SHOULD BE UTILIZED WITH THESE RECOMMENDED CYCLES)
  1. Gravity displacement vessel. The recommended minimum exposure times and temperatures validated for the injector and lens loader with a load size of three (3) reusable surgical instruments are:
    - Thirty (30) minutes at 121°C (250°F).
    - Fifteen (15) minutes at 132°C (270°F).
    - The recommended dry time is a minimum of 30 minutes.
    - NOTE: This validated cycle represents a worst-case scenario representing the shortest duration sterilization cycle which effectively sterilizes the instruments. This is a scenario which is most likely to be used by health care facilities due to the type of equipment most readily available to sterilize surgical instruments. Should any other type of sterilization method or parameters (i.e., vacuum/temperature/contaminants, without there is a unique configuration, 10 min, 121°C) be used, the user must verify its effectiveness prior to use.
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**LC Cartridge Chart**

<table>
<thead>
<tr>
<th>Cartridge with Silicone Cushion</th>
<th>IOL</th>
<th>Injector</th>
<th>Tip Diameter (mm)</th>
<th>Lenstec IOL Power Range (D)</th>
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<tbody>
<tr>
<td>LC16</td>
<td>Softec HD</td>
<td>IOL11S</td>
<td>1.6</td>
<td>+6.0 to +26.0</td>
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<td></td>
<td>Softec I</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Softec HDM</td>
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**Cart Series Cartridge Chart**

<table>
<thead>
<tr>
<th>Cartridge with Silicone Cushion</th>
<th>IOL</th>
<th>Injector</th>
<th>Tip Diameter (mm)</th>
<th>Lenstec IOL Power Range (D)</th>
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<tbody>
<tr>
<td>Cart45S</td>
<td>Softec HD</td>
<td>IOL11S</td>
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<td>Softec I</td>
<td>IOL12</td>
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<td></td>
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<tr>
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<td>Softec I</td>
<td>IOL12FS</td>
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<tr>
<td>CartM</td>
<td>Softec HDM</td>
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<td>+5.0 to +36.0</td>
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**LEGEND**

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
<th>Symbol</th>
<th>Meaning</th>
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<tbody>
<tr>
<td>![1]</td>
<td>Consult instructions for use</td>
<td>![2]</td>
<td>Do not reuse</td>
</tr>
<tr>
<td>![3]</td>
<td>Use by</td>
<td>![4]</td>
<td>Sanitized using ethylene oxide</td>
</tr>
<tr>
<td>![5]</td>
<td>Prescription use only</td>
<td>![6]</td>
<td>Lot number</td>
</tr>
<tr>
<td>![7]</td>
<td>Do not reuse</td>
<td>![8]</td>
<td>Cautions, Consult accompanying documents</td>
</tr>
<tr>
<td>![9]</td>
<td>Sanitized using ethylene oxide</td>
<td></td>
<td>Temperature limitation</td>
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